

# Study Guide for Response Analyses

## Objectives of this Module

1. Define response analyses and the terminology associated with those analyses
2. Identify the role of response analyses in effects analyses for consultation
3. Identify the process of conducting response analyses
4. Identify strategies for handling evidence in response analyses.
5. Work through practical examples of response analyses

## Introduction

Exposure analyses identify how many individuals of which species are likely to co-occur with an Action's effects and the details of that co-occurrence — what they would be exposed to and how that exposure would vary with space and over time. Given that exposure, it is important to know how those individuals are likely to respond to that exposure. Are they likely to die? Delay reproduction? Produce fewer young or seeds? Grow slower and take longer to mature? Stop feeding? Abandon their territory?

Similar questions follow any exposure analyses for critical habitat. Is the forage base likely to decline in all or a portion of the designated area? Would the area become overgrown? Would temperatures increase (or decrease)? Would the soil or substrate acidify? Would the incidence of fire increase or decrease? Response analyses answer these questions. Response analyses determine how listed resources are likely to respond after being exposed to an Action's effects on the environment or directly on listed species themselves. For habitat-based assessments, response analyses are where we establish relationships between habitat change and a listed species' response to that change. In short, response analyses help translate exposure into risk.

The idea behind response analyses is not new: Service consulting biologists already include the essence of response analyses in biological opinions. However, like exposure and risk analyses, response analyses lend structure to consultations that allows the Services to involve Action Agencies (and any applicant) in the process of assessing the effects of their actions on listed resources. Involving Action Agencies in the process of establishing how listed resources are likely to respond upon being exposed to their Action's effects is an important step in providing transparency to interagency consultations and will help them understand the basis for the Service conclusions.

Response analyses should be driven primarily by the evidence available from published sources (journal articles, conference proceedings, etc.), unpublished sources (reports produced by government agencies, consultancies, institutes, and environmental organizations; doctoral dissertations; and master's theses), and any data that Service biologists may have collected or be able to access. Although some of this evidence will need to be interpreted, most of that interpretation should occur as part of Service risk analyses. As a result, this step of our assess-

ments will be driven by the questions we ask, questions the action agency or applicant ask, the quality of our search strategies, and the information we extract from search results.

### **What Does the “Response” in “Response Analysis” Mean?**

Following this consultation framework, we begin an assessment by subdividing proposed Actions into component parts (which we have called “deconstructing the action”) to increase our ability to detect the various pathways and mechanisms through which Actions affect the natural environment. Then we identify the physical, chemical, and biotic effects of those component parts, following them as they move from their source(s) through landscapes, watersheds, coasts, oceans, and the atmosphere over time.

Armed with that information, we then work with an Action Agency and applicant (if any) to identify the threatened or endangered species and designated critical habitat are likely to be directly affected by an Action’s effects or co-occur with an Action’s effects on the environment (which we have called “exposure analyses”). In addition to determining which listed resources are likely to co-occur with an Action’s effects, these analyses identify where and when the exposure is likely to occur, how frequently the exposure would occur, how long the exposure would occur, and what the listed resources would be exposed to in terms of concentration (for sediments, chemicals, pathogens, etc.), received levels (for noise and other audible disturbance), or similar units of measure.

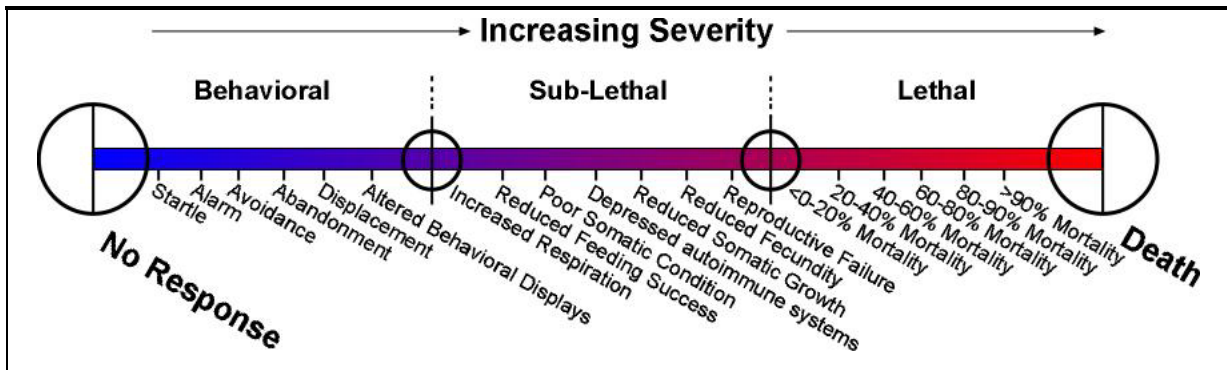
During response analyses, we work with Action Agencies and applicants to identify how listed resources are likely to respond or react upon being exposed to an Action’s effects. The discussions that follow summarize the primary categories of responses we would observe in listed species (treating animals and plants separately), if we used habitat as an index of an organism’s response, and for critical habitat.

### **Listed Species: Animal Responses**

In animals, responses will generally fall into four categories: no response, behavioral responses, sub-lethal responses, and lethal responses (see Figure 1).

1. *No Responses* means no apparent or observed response and encompasses an animal’s normal behavioral repertoire. It is important to remember that we should interpret evidence that suggests species did not respond to human activity cautiously: we should distinguish between “no response” and “no apparent response.” It will often be impossible for human observers to distinguish between an animal’s normal range of responses and its responses to human stimuli.
2. *Behavioral Responses* encompass all behavioral reactions and responses to natural and anthropogenic stimuli. Some of these responses will be reflex responses that an animal would exhibit regardless of the stimulus (for example, an opossum passing out or a vulture “purging” when startled). Some of these responses (such as alert responses or some avoidance) reflect an animal’s awareness — a bald eagle that is aware of a human presence, but the human is still too far away to cause the eagle to flush — rather than adverse reactions to a stimulus (we would not detect any differences in pulse rates, respiration rates, energy charges, or hormones related to stress). Behavioral responses can be acute or chronic and can often be mitigated by habituation, which would cause an animal to become less sensitive to a stimulus (that is, the animal’s response would move toward to left — toward no response — of the scale in Figure 1).

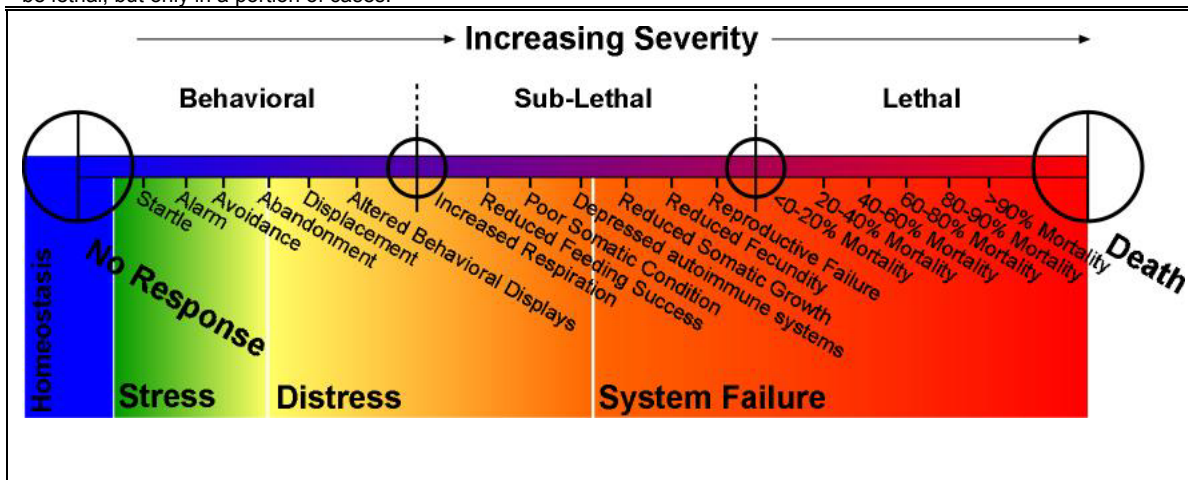
**Figure 1. An illustration of the range of animal responses to physical, chemical, or biotic stressors.** The mortality values in the right end of the spectrum reflect phenomena that are known to be lethal, but only in a portion of cases.



3. *Sub-lethal Responses* encompass the full range of observable symptoms of acute or chronic stress in individual animals that can disable an individual animal but do not kill the animal. Sub-lethal responses include increased respiration (for example, increased panting in terrestrial vertebrates or increased surfacing rates in aquatic mammals), reductions in an animal's foraging activity and foraging success, reduced body condition and reduced growth rates (which can result from reduced foraging success, but can also indicate physiological stress), reduced fecundity and reduced reproductive success (which can result from any of the other sub-lethal responses). Sub-lethal responses can be acute or chronic. Unlike behavioral responses, only some sub-lethal responses can be mitigated by habituation and only some sub-lethal effects are reversible (generally the responses enveloped by the "distress" zone in Figure 2).
4. *Lethal Responses* encompass the range of responses that include some risk of mortality, ending with certain death at the upper end (for example, a desert tortoise or key deer that is hit by a car has some risk of mortality, but death is not certain; in contrast, all darters that are stranded in de-watered pools will die if they are not moved). Lethal responses can be acute or chronic; unlike other responses, lethal responses do not involve habituation and are not reversible.

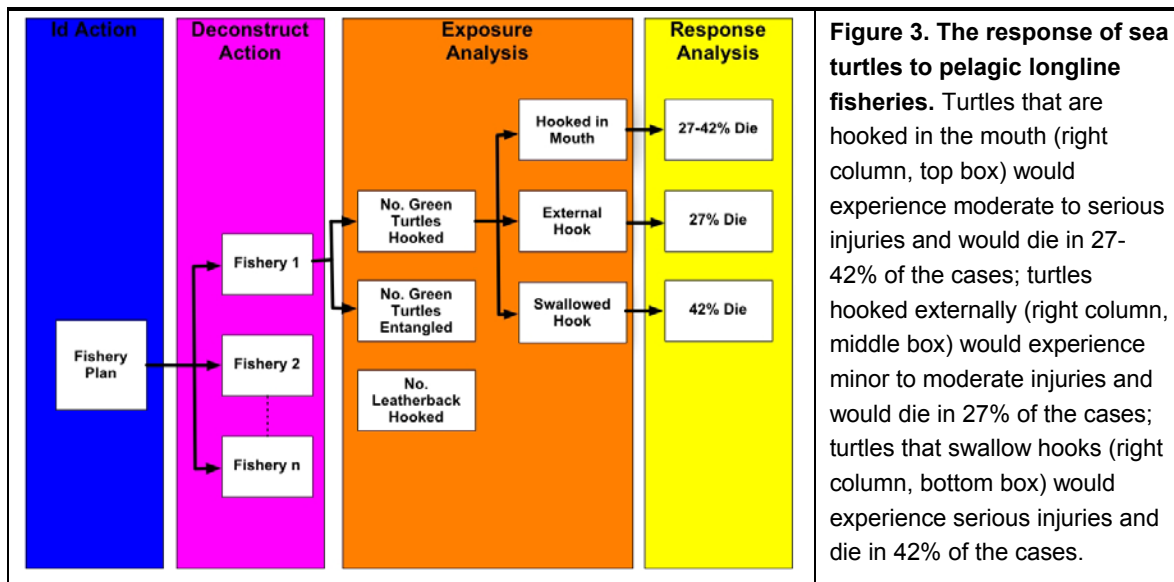
Figure 1 illustrates the range of responses that would be apparent or observable by a human observer, but —absent visual symptoms like depleted somatic condition, disorientation, or disease— these responses provide no information on the internal state of the animal. An animal's internal state, particularly physiological and biochemical indicators of stress, is a more sensitive and robust indicators of an animal's response to environmental stressors (Figure 2). As the left side of Figure 2 illustrates, we might conclude that an animal has had "no response" to an Action's effects when, in fact, the animal is experiencing internal stress (Fair and Becker 2000, Gill et al. 2001). For that reason, when we conclude that an animal has had "no response" to an Action's effects, we have some risk of reaching a false conclusion. That risk increases when we rely on studies or evidence that have not measured the internal state of study subjects (see Baker and Johanos 2002 and Krausman et al. 1998 for examples of studies that examined the effects of human activity on the internal states of listed animals). The risk of falsely concluding "no response" is highest with behavioral and sub-lethal responses which require humans to interpret an animal's behavior or interpret data on an animal's health (which may also result from differences between individuals in a population or environmental change that is unrelated to an Action's effects).

**Figure 2. An illustration of the relationship between an animal's overt responses and the animal's internal state.** As in Figure 1, the mortality values in the right end of the spectrum reflect phenomena that are known to be lethal, but only in a portion of cases.



### Examples

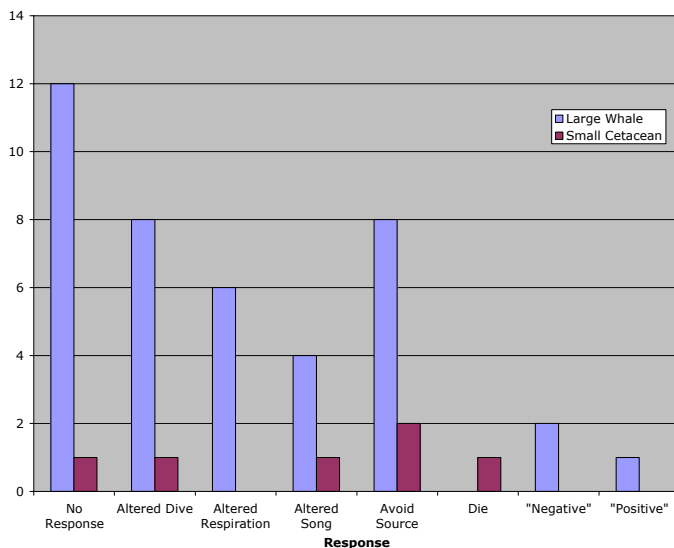
- Pacific Longline Fisheries.** The National Marine Fisheries Service proposed a fishery management plan that encompassed a suite of pelagic fisheries centered off the Hawaiian archipelago, American Samoa, Guam, and Palmyra and Johnston Atolls. The management plan includes Hawaii-based, pelagic longline fisheries for tuna and swordfish that have occurred for more than 15 years. Over that period, NMFS has kept records of the number of different sea turtles that have been caught in the fisheries, that have died as a result or have been released after having been hooked. NMFS convened a group of fisheries experts to estimate the number of sea turtles that would be hooked and released, but would be likely to die later from their injuries (Figure 3).



2. **Low Frequency Sonar.** The U.S. Navy proposed to employ a low frequency active sonar for anti-submarine detection. The sound source would transmit at frequencies between 100 and 330 Hz, with sound pressure levels of 215 dB re: 1  $\mu$ Pa at 1 meter from the source. Pings would last between 6 and 100 seconds, with about 15 minutes between pings. The transmitters would be on for no more than 432 hours per year. The Navy would also employ an active high frequency sonar that is designed to detect marine mammals at least 1,000 meters from the source; if this detection system is effective, cetaceans should not be exposed to received levels above 180 dB re 1  $\mu$ Pa.

*NMFS asked the question:* How would baleen whales be expected to respond when exposed to an acoustic source transmitting for 6 to 100 seconds at frequencies ranging from 100 and 330 Hz and received levels between 120 and 180 dB re 1  $\mu$ Pa?

Literature searches produced 37 documents that met pre-set criteria and provided 69 records of cetacean responses to low frequency sounds (see Figure 3). Based on the available evidence, threatened or endangered cetaceans are likely to respond to low frequency sounds with increased dive times, altered respiration patterns or time at surface, altered song patterns or interrupted songs, or they would show no responses detectable to human observers. The available evidence suggests that exposure to low frequency sonar is not likely to injure or kill threatened or endangered cetaceans, although the same may not be true for small cetaceans like beaked whales.

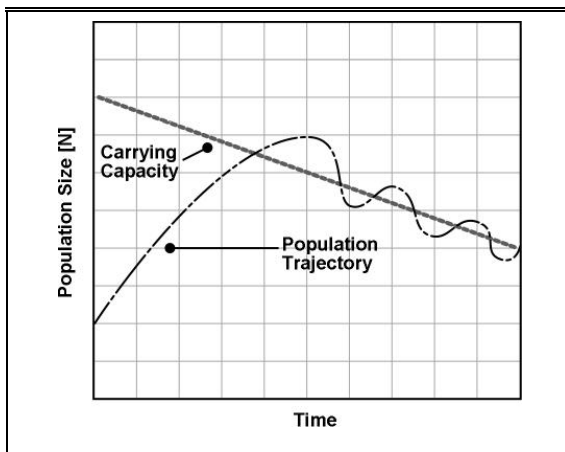


**Figure 4. The range of responses of cetaceans to exposure to different low frequency sounds.** In this range of responses, the “no response” group may include animals that were stressed but showed no outward signs of that stress.

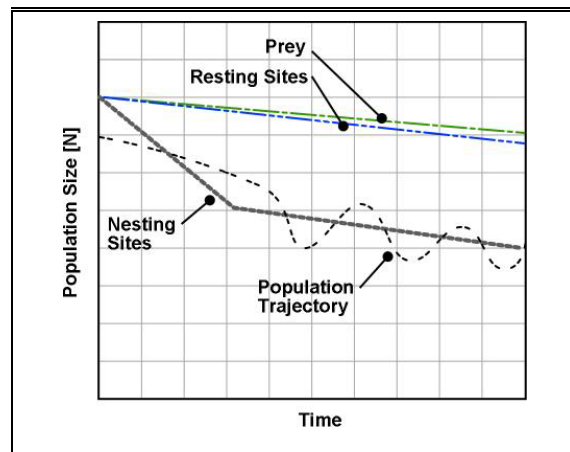
### Listed Species: Habitat as a Proxy for Animal Responses

The Services commonly use habitat as a proxy for species. In fact, habitat-based analyses are one of the most common approaches the Services use to determine how listed species are likely to respond to an Action’s effects. One assumption underlying these assessments is that the loss and fragmentation of habitat would reduce the size of a population of listed resources (Figure 5). Ecologically, it would be more correct to think of “habitat” as a generic term for the physical, chemical, and biotic resources species need to complete all or portions of their life cycles (Figure 6). That is, Actions do not affect “habitat” they affect the physical, chemical, or biotic resources that individual animals (or plants) require; individual animals respond to changes in those

**Figure 5. A generic illustration of a population's response to habitat change**



**Figure 6. A more accurate illustration of the general relationship between “habitat” change and a population's response to that change**



resources (Figure 6).

Habitat-based analyses rely on the relationship between individual animals and the resources they require, but those relationships are often implied rather than established. In consultation, it is important to be specific about relationships between species and their habitats by identifying the actual resources that are likely to be affected by a proposed action because a species' probable response to an Action's effects will depend on the resource being affected. In the situation illustrated in Figure 6, where an Action's effects reduce the number of nesting sites available to a species in a particular area, the species is likely to respond by reduced reproductive success and, possibly, mortality if adults engaged in lethal contests over a nest site (depending on the species, the population could also experience some emigration as unsuccessful adults leave an area in search of suitable nesting sites). However, adults that successfully find nesting sites in the area affected by the Action should reproduce successfully because the Action does not affect their prey base.

The same would not be true if the proposed action affected the prey base but did not affect the number of nesting sites. Reductions in a species' prey base would affect all members of a population, regardless of their gender, age, or stage. Depending on the magnitude of the reduction, the change in the population's prey base would reduce the reproductive success of the animal's occupying the site, increase neonate and juvenile mortality rates (with later effects on the population's age structure), and adult survival rates.

Because an Action's effects on listed species will differ depending on the actual resources the Action would destroy or modify, the Services' habitat-based analyses should be specific rather than generic. For the most part, Actions that affect habitat have an indirect effect on the species (that is, effects that are mediated through habitat). Actions can affect listed species by affecting a species' prey base, by affecting the prey base of a species' competitors or predators, by affecting organisms that have a symbiotic relationship with listed species (plant pollinators, host plants for larval butterflies, or host fish for the glochidia of freshwater mussels for example), or by eliminating ecological processes that are necessary to maintain the quality, quantity, or availability of the resources that comprise a species' habitat (examples include change in an area's fire regime, flood cycle, or the removal of species like native buffalo from prairie

ecosystems at the expense of species like running buffalo clover, *Trifolium stoloniferum*). Our exposure analyses should specifically identify those indirect pathways (to the extent that the available information and our knowledge of ecology allows us to be specific); habitat-based response analyses should do the same.

Finally, populations will generally respond to changes in the feature of their habitat that is the most limiting. The situation illustrated in Figure 6, for example, would have different consequences if the population size was not limited by the quality and quantity of prey, nesting sites, or resting sites; if none of these three habitat features limits the number of individuals an area can sustain, reducing one or more of these three features might not cause the population to respond. Habitat-based assessments assume that particular resources would impose limits on the number of individual animals an area could sustain at a particular level of health. That assumption fails if a population would not be limited by the quantity, quality, or availability of resources as a result of the action. As a result, response analyses should establish that an Action's effects are likely to change one or more features of a species' habitat in ways that can be expected to create new limits on the size of a population or exacerbate limits that already exist.

With habitat-based assessments, it will be important to establish causal relationships between stressor(s), changes in one or more variables in a species' habitat, and a species' response to those changes. In particular, habitat-based assessments need to establish that exposure pathways — or the route(s) that stressors take from their source to listed species or critical habitat — are complete. For habitat-based assessments, this criterion will require us to establish a complete connection from an Action, through a species' habitat, to the species' response to the changes in habitat (and support our assertion with evidence supported by literature) to establish a causal relationship between an Action and a species' response. If exposure pathways are not complete, then stressors associated with an Action do not reach listed species or critical habitat and, therefore, cannot cause a response. Similarly, our assessments also should establish that (a) the exposure would precede the response; (b) the relationship is biologically plausible based on current understanding of physical, chemical, and biotic processes and mechanisms; (c) the association between a stressors and a response has been observed consistently in different studies and in different populations (see Appendix A for more background on causal arguments).

### Listed Species: Plant Responses

In plants, responses will generally fall into four categories: no response, sub-lethal responses, and lethal responses (see Figure 5).

1. *No Responses* usually means “no apparent” or “no observed” response and encompasses a plant's normal growth rate, phenology (annual cycle of seedling emergence, floral development, seed formation, etc.), visual appearance, or fecundity. Because it will often be impossible for human observers to distinguish between a plant's normal range of responses and its responses to a human stimulus, carefully review the experimental designs of studies that conclude “no response” to be certain that the study could have reached that conclusion.
2. *Sub-lethal Responses* encompass the full range of observable symptoms of acute or chronic stress in individual plants that can disable an individual plant but does not kill it. Sub-lethal responses include increased transpiration or other signs of water stress, reductions in the area of vegetative organs, poor condition, reduced growth rates (which indicate water or biochemical stress), reduced fecundity (the number or size of seeds) and reduced vegetative reproduction (in some species, reduced reproductive success or



sexual reproduction can lead to increased vegetative reproduction). Sub-lethal responses can be acute or chronic.

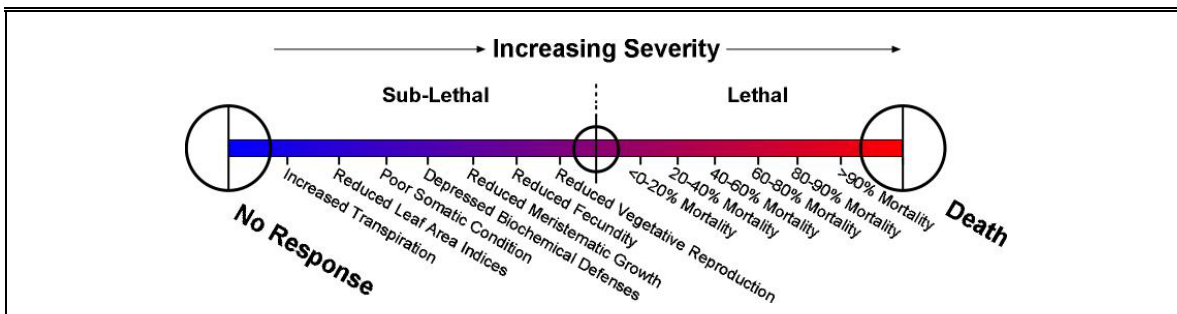
3. **Lethal Responses** encompass the range of responses that include some risk of mortality, ending with certain death at the upper. Lethal responses can be acute or chronic; unlike other responses, lethal responses.

### Responses of Critical Habitat

Our response analyses for critical habitat will follow the general pattern for habitat-based assessments: we will need to identify the actual resources that are likely to be affected by a proposed action because different resources have different implications for how listed species are likely to respond to an Action's effects. Unlike habitat-based assessments, response analyses for critical habitat should establish relationships between an Action's direct and indirect effects and the constituent elements the Services included in the critical habitat designation. In particular, response analyses for critical habitat need to establish relationships between the overall value of the habitat for the conservation of listed species and an Action's effects on specific constituent elements (recognizing that implicit constituent elements would also include spatial variables like the area of critical habitat, its spatial pattern, and connectivity).

**Figure 5. An illustration of the range of plant responses to physical, chemical, or biotic stressors.**

The mortality values in the right end of the spectrum reflect phenomena that are known to be lethal (and, in plants, can include grazers or disease), but only in a portion of cases.



### Things to Keep in Mind When You Conduct Response Analyses

1. **Response analyses allow you to translate exposures into risk.** Response analyses provide structured answers to questions about what will happen to threatened and endangered species and designated critical habitat when those listed resources are exposed to different effects of Action's on the environment. The more carefully you structure your response analyses, the more robust your conclusions.
2. **Response analyses should be driven primarily by the available evidence.** Although this will require you to gather evidence and evaluate any evidence you gather for reliability and relevance, these analyses should be as objective as possible. Treating response analyses as process of answering a series of neutral questions using the available evidence will help achieve this outcome.
3. **Tailor your response analyses to the probable exposure.** Response analyses should be specific to the Action's effects as they will occur in space and over time, recognizing that the intensity of those effects will often attenuate over space and time. As we prepare our response analyses, we need to remember that stressors — like sediment loading,



some biocides, and sounds — can become less intense with increasing distance from a source and they can also become less intense as time passes, even close to a source. For example, a prairie-fringed orchid (*Platanthera* spp.) that is exposed to an herbicide near the source of the application will probably exhibit different responses than the same orchid that is affected by wind-borne drift a kilometer from the application. Similarly, sedimentation would elicit different responses from species like Neosho madtom *Noturus placidus*, loach minnow *Tiaroga cobitis*, or steelhead smolt depending on the distance of those species from the source of the sediment; the species response might also change if the species is exposed to the sediment a few days, a week, or a month after the discharge occurred (in the latter case, the species might be exposed to both coarse and fine particles if it was in the area during the sediment discharge, but might be exposed only to fine particles after the coarse particles precipitated from the water column).

4. **Tailor your response analyses to the listed resource.** A plant's or animal's response to a stressor will often depend on its age or stage, sex, and its health condition and health history prior to being exposed to the new stressor. For example, seeds in a seed bank will have different responses to light, crown fires than mature, annual plants; glochidia will have different responses to suspended sediment than adult mussels. Your response analyses should be sensitive to the age(s) or stage(s) of the listed resources that would be exposed to an Action's effects; health condition of the individuals; the timing of that exposure in the annual cycle of listed resources (many animals may exhibit responses during one part of their annual cycle and not at others).
5. **Establish causal relationships between exposure and response.** This is an important step with any assessment approach, but is particularly important with habitat-based assessments (see Appendix A for additional recommendations on this step). If you cannot establish a causal relationship between exposure to an Action's effects and a listed resource's response or if you cannot articulate why there is a causal relationship, you should re-evaluate your assessment.
6. **Structure your response analyses to protect against Type II error.** As always, concluding that a listed resource would have no response to an Action's effects when, in fact, the resource would have substantial, adverse responses, could place the species at greater risk of extinction. You increase your chances of Type II error if you fail to identify potential responses, particularly sub-lethal or lethal responses. You can minimize this risk by verifying the depth and breadth of your personal knowledge through careful searches of the scientific literature and other evidence (see the next section and the Evidence module of this course).

### Search Strategies to Support Response Analyses

**Step 1. Convert the results of your exposure analyses into answerable questions about responses. These questions should be posed in the most neutral language possible to avoid biasing any search results. For example:**

- How would baleen whales be expected to respond when exposed to an acoustic source transmitting for 6 to 100 seconds at frequencies ranging from 100 and 330 Hz and received levels between 120 and 180 dB re 1  $\mu$ Pa?
- How would roosting Indiana bats be expected to respond to forest fragmentation?

- How would roosting Indiana bats be expected to respond to mechanical sounds from machinery associated with timber cuts?
- How would foraging Indiana bats be expected to respond to forest fragmentation?
- How would sentry milk vetch (*Astragalus cremnophylax* var. *cremnophylax*) be expected to respond to human trampling?
- How would loggerhead sea turtles respond to being hooked in pelagic, longline fishing gear?

You should structure each question using neutral language (“How would Species A be expected to respond”? not “Would Action A kill Species A”?). Neutrally-phrased questions will allow you to gather evidence that covers the entire range of possible responses — positive, negative, and no response — rather than just negative responses.

## Step 2. Build a search strategy around these questions

Your search strategy should identify the indices or databases you plan to use and what keywords you plan to use to conduct your searches. You should always remember to enter those keywords into internet search engines like Google, Yahoo, and Lycos as well as databases that index scientific and technical literature.

The Library of Congress’ *First Search* and Cambridge Abstract’s *Aquatic Sciences and Fisheries Abstracts* (ASFA) database provide access to most of the recent, technical literature that is relevant to response analyses. *First Search* provides access to a number of databases: *Agricola*, which indexes about 5,000 journals on entomology, natural resource conservation, and plant disease that have been published since 1970; *ArticleFirst*, which indexes about 12,000 printed sources published since 1990; *BasicBiosis*, which indexes 350 sources specific to the physical and biological sciences; and *PaperFirst* and *Proceedings*, which index conference proceedings. *ASFA* provides access to journal articles, magazine articles, and conference proceedings specific to aquatic species and aquatic ecosystems back to 1964.

**Table 1. A sample search string to gather evidence on the effects of low frequency sound on listed whales. For example, ArticleFirst was searched once using “sonar” AND “pinniped” AND “effect”; it was searched a second time using “sonar” AND “pinniped” AND “response”; etcetera.**

Keywords	Paired With Keywords (using “AND”)	Modified Using Keywords (using “AND”)
sonar, low frequency sonar, acoustics, marine acoustics, sound, noise	dolphin, fish, marine fish, marine mammal, pinniped, porpoise, salmon, sea turtle, sea lion, monk seal, whale	effect, impact, response
ecological risk assessment, ecological risk analysis, risk	noise, sonar, sound	

Because response analyses should be based on evidence, with limited interpretation, we can use a wide variety of sources to gather evidence (beyond the Action Agency and applicant): we can ask environmental groups, academicians, State personnel, Tribal governments and tribal members, local governments, and citizen experts for evidence they might have that is relevant to a consultation. However, when we ask groups other than an Action Agency or applicant for evidence, we have an additional responsibility to

be certain that we have tried to gather all potential evidence not just evidence that is biased or that might lead a particular conclusion.

### **Step 3. Summarize and analyze the results of your search**

When you review the evidence you gather to identify listed resources' probable responses to an Action's effects, you will need to examine the study's design to determine the degree to which you can use the study as part of your analyses. Obviously, some study designs will be more robust than other study designs. You will need to consider the sample size produced by a study, the effect size, whether the study controlled for confounding effects (or other stimuli that could have caused the responses the study identified), similarities between the sources used in a study and the stressor you're considering in a response analysis, and similarities between the conditions of exposure.

In the example presented earlier on low frequency sonar (page 4, example 2 and page 5, Figure 4), the most robust studies were *controlled exposure experiments* that allowed investigators to determine that specific animals were responding to a particular, low frequency source and not some other stimulus.

Another aspect of study designs that is important to response analyses is the degree to which a study allowed subjects to exhibit a wide range of potential responses to a stimulus. If a study limits an animal's potential responses to a stimulus, you may not be able to use the study for your response analyses. For example, Popper *et al.* (2002) and McCauley *et al.* (2003) studied the effects of low frequency sounds on several species of marine fish. Unfortunately, their study designs constrained the experiments of their subjects in ways that prevented the fish from moving away from the source of the low frequency sound which would have allowed them to avoid exposures that might be harmful (which fish would normally do in the wild). Because these studies artificially forced fish to be exposed to sounds at received levels that injured them (received levels the fish would have avoided in a natural setting), it would be inappropriate for us to use these studies as the basis for response analyses to exposures in natural settings. This will be a common limitation of controlled experiments, particularly laboratory experiments: the exposures they represent rarely represent exposures in natural environments.

### **Step 4. Identify probable responses from your analyses**

During response analyses, you should avoid trying to decide if an animal's behavioral responses to human environmental change constitute "harm" or "harassment" for the purposes of "take." At this stage of your analyses, you should focus on identifying the range of a species responses to an Action's effects, particularly changes in behavior that have known relationships to a species' survival or reproductive success and (in animals) immigration and emigration. You will determine if those responses constitute "take" in the next step of your analyses: risk assessment.

For controversial consultations or consultations that might be litigated, you might want to submit the results of your response analyses for peer review. As part of routine consultations, you may want to provide Action Agencies and applicants with an opportunity to review and comment on the results of your response analyses (see further discussions under Strategies for Working With Action Agencies and Applicants, next page).

## Dealing with Uncertainty and Unknowns

Despite the wealth of information available, you will encounter some situations where there is no evidence. In those instances, you will need to use surrogates and make inferences about the probable responses of listed resources based on the responses of those surrogates. The best approach to using surrogates is to move up through a species' taxonomic sequence: that is, start with sub-populations, move to populations, then subspecies, species, genus, family, class, and order. You need to remember that as the taxonomic group you may use as a surrogate becomes more removed from the listed species, you increase the risk of coming to a false conclusion.

You can reduce the risk of false conclusions by comparing the life cycles of your surrogates with the listed species (try to compare long-lived species with other long-lived species, compare species with delayed maturity with other species that also have delayed maturity) and comparing the trophic position and ecologies of the two species (try to use top or mid-level predators as surrogates for other top or mid-level predators), and comparing species with analogous vital rates (try to compare slow-growing populations — that is, populations with low rates of increase — with other slow-growing populations). Rather than use a single surrogate, try to use multiple surrogates and make inferences from the entire set.

## Strategies for Working with Action Agencies and Applicants

Although agencies have become accustomed to initiating consultations, then waiting to receive biological opinions, nothing requires the Services to do all of the work of consultation. During consultation, the Services can task Action Agencies, applicants, or both to help the Services conduct response analyses. They (or their consultants) can conduct literature searches, gather other evidence for response analyses (for example, monitoring reports), as well as analyze the results of those searches.

Tradition will be the primary obstacle to using this kind of strategy: Action Agencies have become accustomed to initiating consultation then waiting for a biological opinion. Agencies will assume that once they have submitted a Biological Assessment and the information they must submit to initiate formal consultation (see 50 CFR 402.14(c)), that their responsibilities have ended. It is important to remember that this information is required to initiate a consultation, it is not the consultation itself.

As we have discussed several times in this course, you can help change that tradition by telling Action Agencies and applicants how you plan to conduct your assessment when you begin your consultation. During that discussion, you can establish the roles and responsibilities and expectations. When you respond to an Agency's request to initiate formal consultation, you can also tell them that although they have provided the information that is required to *initiate* formal consultation, additional information or analyses may be required to complete the analyses that are required to complete formal consultation (note that this strategy allows that our regulations only identify the information required to *begin* a consultation which may be different than the information that is required to *complete* a consultation).

As always, it is important to remain reasonable with your requests and your expectations. You should not ask Action Agencies or applicants to provide you with information or analyses that you already have or that you can access more easily than they can (for example, if the information is generated by Service personnel or by a State agency with Federal aid funds or recover funds, the Services would have more access to that information than most Action Agencies). You should not ask Action Agencies or applicants for analyses they cannot conduct or do not know how to conduct.

When you have complete your response analyses, you should consider providing Action Agencies and applicants with an opportunity to review and comment on your results (this will be more important in controversial consultations). Their review should be limited to substantive issues that can be supported with evidence, such as:

1. our analyses omitted or neglected information or evidence that might lead to different conclusions (with the evidence provided or referenced), or
2. our search strategy omitted or neglected sources of relevant evidence (with the sources provided or referenced).

If you receive comments on response analyses, make certain that your administrative record contains your written response to those comments.

### **Documenting Response Analyses**

When your response analyses are complete, the administrative record for your consultation should have:

1. Any correspondence between the Services, Action Agencies, and applicants the relate to these analyses;
2. Copies of literature searches you, Action Agencies, or applicants might have conducted to complete these analyses, supported by specific information on the search strategy that was used to gather evidence;
3. Memoranda to the consultation file that identifies the information you used in your analyses, evidence you discounted for your analyses (and an explanation of why), how you analyzed any evidence in your analyses, and the results your analyses produced;
4. Letters, e-mail messages, memoranda, or other documentation of any reviews of your response analyses and how you addressed any comments you received.

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## Appendix A: Approaches to establishing causal relationships

When we assert that a listed species or critical habitat would respond in a particular way to an exposure, we are asserting that the exposure “causes” a response. As a result, it is important to provide sufficient information to support our causal assertion. Different applied sciences use various approaches for establishing or detecting causal relationships (that is, for relating causes to their effects), but all of them rely on building causal arguments. There are two basic forms of causal arguments (1) arguments that rely on “necessary” conditions and “sufficient” conditions and (2) arguments that rely on sets of rules for assembling or building causal arguments.

### Cause as a “Necessary” Condition, a “Sufficient” Condition, or Both

A stressor is a “necessary cause” of a response when the stressor must precede the response, even if the response is not the sole result of that single stressor. A stressor is a “sufficient cause” of a response when the inevitably produces a response. As explained below, a given stressor can be “necessary cause” of a response, a “sufficient cause”, neither, or both.

1. *Stressor X is Necessary and Stressor X is Sufficient to cause Response Y.* In this instance, Stressor X and Response Y are always present together, and nothing but Stressor X is needed to produce Response Y ( $X \rightarrow Y$ ). This causal relationship is strengthened when only Stressor X leads to Response Y (see also SPECIFICITY OF CAUSE, below). For example, direct exposure to *Toxoplasma gondii* can be necessary and sufficient to cause the disease *toxoplasmosis* in wildlife like the ‘Alala (the Hawaiian crow), other members of the crow family, or other wildlife.
2. *Stressor X is Necessary but Stressor X is not Sufficient to cause Response Y.* In this instance, Stressor X must be present when Response Y is present, but Response Y is not always present when Stressor X is. As a result, some additional factor(s) must also be present with Stressor X to produce Response Y. Continuing with the previous example, domestic and wild cats are the only known vector for *Toxoplasma gondii* and spores for the protozoan occur in the feces of infected cats, so cats and cat feces (Stressor X) are necessary for toxoplasmosis, but not all cat feces contain active or dormant spores. Therefore, cats and cat feces are necessary for toxoplasmosis (they must always be present), but they are not sufficient to cause toxoplasmosis (spores for the protozoan *T. gondii* must also be present to cause the disease).
3. *Stressor X is not Necessary but is Sufficient to cause Response Y.* Response Y is present when Stressor X is present, but Response Y may or may not be present when Stressor X is present because Response Y has other causes and can occur without Stressor X (see also SPECIFICITY OF EFFECT in which Stressor X may lead only to Response Y, but other factors may also lead to Response Y). For example, harvesting adult animals in excess of recruitment rates is sufficient to cause a population to decline, but is not a necessary cause of population decline: populations can decline in the absence of overharvesting adults (for example, habitat loss, or overharvesting eggs are also sufficient to cause a population to decline).
4. *Stressor X is neither Necessary nor Sufficient to cause Response Y.* In this instance, Stressor X may or may not be present with Response Y is present. Under these conditions, if Stressor X is present with Response Y, some additional factor must also be present, which leaves Stressor X as a contributing cause of Response Y.

## Causal Relationships Established Using Arguments Based on Assembly Rules

In 1856 John Stuart Mill published *A System of Logic*, which proposed logical strategies for inferring causal relationships that are still used in applied sciences like epidemiology and geology. For example, John Snow used an inquiry based on a series of criteria when he was tasked with identifying the “cause” of a cholera outbreak in London in the late 1800s, an investigation that formed the basis for modern epidemiology. More recently, several authors have proposed logical rules for assembling causal arguments or establishing causation for the purposes of applied sciences, ecological risk assessment, or both (for examples of these assembly rules applied to ecological assessments, see Adams 2003, Collier 2003, Norton *et al.* 2002a, 2002b, 2002c, 2002d).

Assembly rules proposed by Hill (1965) and Evans (1976) and modified by Beyers (1998), and Susser (1991) reconcile the various assembly rules that have been proposed for causal arguments:

- a. **Exposure Preceded Response:** A listed resource must have been exposed to a stressor before a response occurred (this is an essential criterion that stems from the definition of cause). Therefore, as we have discussed in the previous module (*Exposure Analyses*) we have to establish exposure before we can link that exposure to a putative response. However, remember that in the case of chronic diseases, ecological relationships, and phenomena like population or species’ extinction, the exposure may have occurred hours, days, or months before a listed species responds, which will often obscure the relationship between exposure and a response.
- b. **Exposure Pathways Are Complete:** Our assessments need to establish that exposure pathways (or the route(s) that stressors take from their source to listed species or critical habitat) is complete. If exposure pathways are not complete, then a stressor does not reach the listed species or critical habitat and, therefore, cannot cause a response.
- c. **The Relationship is Biological Plausible:** The association between a stressor and a response must be biologically plausible based on current understanding of physical, chemical, and biotic processes and mechanisms. Although statistically significant associations must be present before any relationship can be said to exist, only biologically plausible associations can result in “biological significance.” *However, judgments on this basis are bound by the imperfect knowledge existing at any time.* An association that doesn’t appear biologically credible today may be credible when tomorrow brings us more information. As Sherlock Holmes advised Dr. Watson, “when you have eliminated the impossible, whatever remains, *however improbable*, must be the truth.”
- d. **There is Strength of Association:** A stressor and a putative response must have co-occurred in space and time unless the pathway that connects a stressor and a response is indirect. The latter will be more common in habitat-based arguments because the stressor might affect some characteristic of a species’ habitat — such as the prey base — which then affects the species.
- e. **There is a Biological Gradient:** Any response that is proportional to a stressor’s concentration in the environment suggests a causal relationship between the stressor and the ecological entity’s response. However, causal relationships need not be linear or monotonic; in some, there is a marked threshold, others are sigmoid, and yet others are parabolic. If the association is one that can reveal a biological gradient or dose response, we should look carefully for such evidence. If the response is measured as a function of

- comparative incidence, this condition will ordinarily be met. although the presence of a regular dose-response relationship is highly supportive of the hypothesis, its absence has little bearing on whether an association is causal or not. Experimental evidence is often telling but seldom available for free-living populations prior to remedial action. However, the results of interventions or remedial action, in terms of altered frequency or intensity of the associated events, can provide the strongest support for the causal hypothesis.
- f. **The Association is Specific:** refers to the precision of the association between X and Y. *Does X lead only to Y* (specificity of effect), *or does only X lead to Y* (specificity of cause)? For example, exposure to *T. gondii* (direct or indirect) is a specific cause of toxoplasmosis and toxoplasmosis is a specific effect of that exposure. If we can establish that a stressor is a specific cause of a response, our response analyses will be much stronger. However, it is illogical to expect causes of a given effect to be without other effects. Everyday experience teaches us repeatedly that single events may have many effects.
  - g. **The Association is Analogous to Other Cases:** The association between a stressor and a response should be similar to other well-established cases and should involve analogous mechanisms of exposure. That is, if you cannot establish a causal relationship between a stressor and a response in a particular consultation, you should search the literature for analogous situations with similar species or similar pathways and mechanisms of exposure
  - h. **The Evidence is Coherent:** The association between a stressor and a response should explain inconsistencies among the various lines of evidence.
  - i. **The Association is Consistent:** The association between a stressors and a response should have been observed consistently in different studies and in different populations. The question of coherence includes to questions about biological plausibility and biological gradients.
  - j. **The Association has Predictive Performance:** The association between a stressor and a response makes it possible to make and inform predictions that could not be made or confirmed without that association.
  - k. **The Association is Supported By Experiment:** The association between a stressor and a response responds to experimental manipulation.

### How Do These Approaches Work?

Both of these approaches require you to assemble all of the evidence available to you: information on exposure (that is, any co-occurrence between an Action's effects and listed resources) and information on species' responses to being exposed in analogous situations. For the first approach to establishing causal relationships, examine the evidence you have assembled to determine which of those causal relationships the evidence supports. With the second approach, ask the eleven questions listed sequentially and use the evidence you have assembled to answer each questions in turn. The more an association meets all of these criteria, the stronger our claim of a causal relationship between a stressor and a listed resources' response.